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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,300	11/10/2003	David H. Parma	NEX40CUSDC2	8392
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EXAMINER SHIN, DANA H				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/705,300

Applicant(s)

PARMA ET AL.

Examiner

DANA SHIN

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65,66,68-70 and 72-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65,66,68-70 and 72-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2007 has been entered.

Status of Claims

Currently, claims 65-66, 68-70, and 72-89 are pending and under examination on the merits.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 74, 76, 80, 82, 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 74, 80, and 86 recite the limitation "said adenines" in line 2. There is insufficient antecedent basis for this limitation in the claims.

Claim 76 and 82 recite the limitation "said ligand" in line 3. There is insufficient antecedent basis for this limitation in the claims, because only the term "nucleic acid ligand" precedes the limitation.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65-66, 68-70, and 72-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'." (*Wands*, 8 USPQ2d 1404). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction

provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Below are the factors analyzed to determine the enablement requirement.

(A) The breadth of the claims

In the instant case, claims 65-66, 68-70, and 72-89 are solely directed to therapeutic methods for treating a lectin-mediated platelet disorder, a lectin-mediated inflammation, a lymphocyte trafficking disorder in a mammal and methods for inhibiting platelet adhesion to neutrophils or leukocytes in the blood of a mammal, comprising administering a nucleic acid ligand (aptamer) to L-selectin or P-selectin.

(B) The nature of the invention

The instantly claimed invention is characterized as gene therapy comprising administering an aptamer to a mammal.

(C) The state of the prior art

The earliest filing date sought in the instant application June 7, 1995. See page 21 of applicant's reply filed on May 23, 2007. The state of the prior art pertaining to gene therapy utilizing aptamer technology for treating a lectin-mediated platelet disorder, a lectin-mediated inflammation, a lymphocyte trafficking disorder in a mammal or inhibiting platelet adhesion to neutrophils or leukocytes in the blood of a mammal, as claimed in the instant case was far from being well-established at the time the invention was made in 1995. In addition, there is no prior

art of record that teaches appropriate guidelines to practice gene therapy for treating various diseases or conditions in a mammal as claimed in the instant case.

Applicant has submitted references pertaining to P-selectin- and L-selectin-related aptamer technology. It is noted that neither of the two references (Jenison et al. for P-selectin aptamer and Watson et al. for L-selectin aptamer) are prior art references to the instantly claimed invention, because the Jenison et al. reference was published in August 1998 (more than three years after the priority date sought in the instant application) and the Watson et al. reference was published in April 2000 (almost five years after the priority date sought in the instant application). Besides the fact that neither of the references is a *bona fide* “prior” art reference, neither of the references is representative of the claimed invention. For example, Jenison et al. taught that SELEX-identified P-selectin aptamers bind to P-selectin expressed on thrombin-activated platelets *in vitro*, thereby inhibiting the binding of P-selectin to neutrophils *in vitro*. Furthermore, Jenison et al. taught that “Extrapolating from their *in vitro* characteristics, these novel P-selectin-specific antagonists may be suitable candidates for therapeutic development.” See the abstract. As such, even the Jenison et al. reference published three years after the priority date sought in the instant case was clear on the fact that therapeutic or *in vivo* applications of P-selectin aptamers were not even attempted as of August 1998. Further, Watson et al. taught pharmacological profiles of L-selectin aptamers *in vivo* and suggested that “properly formulated aptamers have the capacity to be effective therapeutics against intravascular targets”. See the abstract. As such, the “capacity to be effective therapeutics against intravascular targets” for L-selectin aptamers was known in the art in April 2000, five years after the priority date sought in the instant case. Hence, no single reference submitted by applicant in support of the enablement

requirement is commensurate in scope with the claimed invention, and moreover, those references submitted by applicant clearly demonstrate the nascent state of the aptamer-mediated gene therapy at the time the invention was made in 1995.

(D) The level of one of ordinary skill

Applicant's submission of P-selectin- and L-selectin-related post-dated references demonstrates that the level of ordinary skill in the art at the time of the invention was relatively low with regard to how to practice the entire scope of the claimed invention. Further, since the gene therapeutic technology such as the claimed aptamer technology for treating a lectin-mediated platelet disorder, a lectin-mediated inflammation, a lymphocyte trafficking disorder in a mammal and methods for inhibiting platelet adhesion to neutrophils or leukocytes in the blood of a mammal was considered nascent as detailed above, one of ordinary skill in the art would not have known how to practice the entire scope of the claimed gene therapeutic methods without specific guidance from the inventor or without performing undue experimentation.

(E) The level of predictability in the art

The unpredictability of *in vivo* inhibitory activity of aptamers remained unresolved until April 2000 as evidenced by the teachings of Watson et al. (citation submitted by applicant). As evidenced by the post-dated reference of Watson et al., delivering aptamers into the appropriate target cell or tissue or blood of a mammal with a requisite treatment effect was not known in the art at the time of the invention. Therefore, it is concluded that the unpredictability of inhibiting L-selectin or P-selectin activity via L-selectin- or P-selectin-binding aptamers was recognized in

the art as of the earliest filing date sought in the instant application.

(F) The amount of direction provided by the inventor

The instant specification is silent about specific direction/guidance commensurate in scope with the claimed therapeutic methods. That is, the specification does not provide any direction that is even remotely related to the claimed gene therapeutic invention for treating a lectin-mediated platelet disorder, a lectin-mediated inflammation, a lymphocyte trafficking disorder in a mammal or inhibiting platelet adhesion to neutrophils or leukocytes in the blood of a mammal. The specification provides only generic and prophetic teachings such that “because of their ability to selectively bind lectins, the nucleic acid ligands to lectins described herein are useful as pharmaceuticals. This invention, therefore, also includes a method for treating lectin-mediated diseases by administration of a nucleic acid ligand capable of binding to a lectin”. See page 19.

The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The “amount of guidance or direction” refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. See *Chiron*

Corp. v. Genentech Inc., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004):

“Nascent technology, however, must be enabled with a specific and useful teaching. The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee’s instruction. Thus, the public’s end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology.” See also MPEP §2164.03. (emphasis added)

(G) The existence of working examples

Applicant argues that working examples 13H and 20 describe human L-selectin aptamers on lymphocyte trafficking in an *in vivo* system. First, the experiments described in examples 13H and 20 are not commensurate in scope with the claimed invention because they do not demonstrate that L-selectin aptamers (SEQ ID NO:193 or 194) capable of inhibiting trafficking of lymphocytes to PLN and MLN can be used to treat a lectin-mediated inflammation or lymphocyte trafficking disorder, as claimed in the instant case. For instance, lymphocyte trafficking disorders recognized in the art include systemic lupus erythematosus (Scrieber et al. (*Rheumatology International*, 1986, 6:215-219) and psoriasis (Camp et al., *Journal of Investigative Dermatology*, 1990, 95:22S-23S). The SCID mouse model used in examples 13H and 20 does not represent any of the lymphocyte trafficking disorders known in the art and therefore, the experimental results showing inhibition of lymphocyte trafficking by L-selectin aptamers do not demonstrate the treatment effect required by the claims.

Applicant also argues that working examples 27-34 show *in vivo* properties of 2'-F RNA ligands to P-selectin. Contrary to applicant’s argument, none of the working examples pertains to

in vivo characteristics of P-selectin aptamers, nor do they show that the P-selectin aptamers are capable of treating a lectin-mediated platelet disorder or inhibiting platelet adhesion to neutrophils or leukocytes in the blood of a mammal, as claimed in the instant case.

Applicant argues that no working examples are required to enable a patent application by citing Court decisions made in *In re Borkowski*, *Cross v. Iizuka*, and *United States v. Telectronics, Inc.* It is noted that the case laws cited by applicant are irrelevant to the enablement issue for the instantly claimed subject matter for the following reasons:

First, the invention claimed in the *In re Borkowski* case is a method of preparing oxygenated hydrocarbon. The Court decided that the lack of working example in the specification is permissible in the *In re Borkowski* case considering the nature of the claimed invention (preparation of oxygenated hydrocarbons) and the fact that only a few hours of experimentation are required for the claimed invention, and therefore one of ordinary skill in the art would have been able to practice the claimed invention without an undue amount of experimentation. Unlike the invention claimed in the *In re Borkowski* case, the instantly claimed *in vivo* therapeutic methods require more than "only a few hours of experimentation" and the nature of the instantly claimed invention is therapeutic while that of the *In re Borkowski* case is a preparation method for a chemical compound, which does not require a living mammal or a treatment effect in the living mammal.

Second, as for *Cross v. Iizuka*, the pharmaceutical compound at issue was imidazole derivative, whose pharmacological activity was tested in a microsome system. The crux of the enablement issue in *Cross v. Iizuka* was the dosages for the claimed compound. The Court stated that one of ordinary skill in the art could determine appropriate dosages for the claimed

compound in the microsome environment without undue experimentation based on documentary as well as testimonial evidence. Furthermore, the Court stated that the specification (Japanese priority document) disclosed a molar concentration of some probative value for an enabling disclosure, such that one skilled in the art could determine the necessary molar concentrations for the imidazole derivative. In the instant case, however, the specification has failed to provide a specific, useful teaching such as the one provided in the Japanese priority document of Iizuka. Furthermore, the claimed L-selectin or P-selectin aptamers are not a derivative of a well-known pharmaceutical composition, which was the case for *Cross v. Iizuka*. Hence, there is no relevant correlation between the cited *Cross v. Iizuka* and the enablement issue confronted in the instant case.

Third, the claim at issue in the *United States v. Teletronics, Inc.* case is directed to a system for expediting the healing of bone fractures and bone defects in a living being. The Court in the *United States v. Teletronics, Inc.* case stated that “it is undisputed that the patent disclosure are enabling with respect to stainless steel electrodes, with the range of current for such electrode set out in the specification...The appropriate levels of current for other electrodes to promote bone growth and avoid fibrous tissue could, therefore, be determined...The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Since one embodiment is admittedly disclosed in the specification, along with the general manner in which its current range was ascertained, we are convinced that other permutations of the invention could be practiced by those skilled in the art without undue experimentation.”

As previously stated in the prior Office actions dated November 147, 2006 (see pages 6-11) and June 12, 2007 (see pages 3-6), the instant specification does not provide any adequate working examples commensurate in scope with the claimed invention. Again, the working examples in the specification do not whatsoever reflect therapeutic efficacy of an aptamer binding to L-selectin or P-selectin.

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure

The individual assessment of the factors (A)-(G) and the combined view of the totality of the factors do suggest that one of ordinary skill in the art would not have been able to practice the entire scope of the claimed invention without undue experimentation at the time of the invention.

See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991), in which it was clearly presented that a rejection under 35 U.S.C. 112, first paragraph for lack of enablement was appropriate, given the relatively incomplete understanding in the biotechnological field involved, and the lack of a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims.

In view of the totality of the factors listed above and the reasons stated above, the claims are rejected as failing to comply with the enablement requirement as set forth in the first paragraph, 35 U.S.C. 112.

Claims 75, 81, and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are newly entered in the instant case and they recite limitations that were not recited previously or those that are not adequately described in the specification. Applicant has pointed out where the new claims is supported; however, the passages pointed out by applicant do not appear have a written description of the claim limitations for a 38mer of SEQ DI NO:206 (which applicant identifies as SEQ ID NO:223) that is "further modified with 2'-OMe purine substitutions" in the specific nucleotides (which applicant identifies as SEQ ID NO:391). Applicant has specifically pointed out pages 65-66 and 72. Although there is a teaching that states "up to 15 positions may be substituted with only slight losses in affinity", pages 65-66 and 72 of the specification do not provide a teaching or description for the claimed limitations for the specific nucleotides with specific chemical modifications such that said 38mer is "further modified with 2'-OMe purine substitutions" in nucleotides at 7-9(GAG), 15(A), 27-28(AG), 30(A).

Accordingly, the claim limitation is considered to introduce new matter which is not adequately described in the application as originally filed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 65-66, 68-70, 72-74, 76-80, 82-86, and 88-89 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,544,959 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth below:

The instant claims are directed to methods for treating a lectin-mediated platelet disorder or a lectin-mediated inflammation or a lymphocyte trafficking disorder comprising administering a nucleic acid ligand to a lectin, wherein said lectin is P-selectin or L-selectin and said nucleic acid ligand is SEQ ID NO:206 or SEQ ID NO:185. Claim 1 of U.S. Patent No. 6,544,959 B1 broadly recites a method for treating a lectin-mediated disease comprising administering a pharmaceutically effective amount of a nucleic acid ligand to a lectin.

It is noted that the specification can be used as a dictionary to learn the meaning of a term in the patent claim. *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999) (“[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning.”); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) (“Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings.”)

The specification of the issued patent discloses that the term “lectin-mediated disease” encompasses a variety of leukocyte-mediated disease states including inflammation and coagulation and teaches that lectin antagonists may have therapeutic applications in treating lectin-mediated inflammation and coagulation. See column 2, lines 18-27. More specifically, the

specification teaches that L-selectin mediates the homing of lymphocytes to peripheral and mesenteric lymph nodes and P-selectin mediates the adherence of platelets to neutrophils and monocytes. See column 2, lines 40-45. To summarize, the specification of U.S. 6,544,959 B1 clearly suggests that lectin-mediated platelet disorder, a lectin-mediated inflammation, and a lymphocyte trafficking disorder are subtypes of the "lectin-mediated disease" claimed in U.S. 6,544,959 B1. As such, the scope of patent protection sought by the broadly claimed methods of U.S. 6,544,959 B1 embody methods for treating a lectin-mediated platelet disorder and a lectin-mediated inflammation in light of the reasons stated above. Furthermore, the aptamer sequences for "L-selectin" and "P-selectin" claimed in claims 6 and 7 of U.S. Patent No. 6,544,959 B1 are identical to those claimed in the instant case. Since the method steps recited in claims 1-7 of U.S. Patent No. 6,544,959 B1 overlap in scope with claims 65-66, 68-70, 72-74, 76-80, 82-86, and 88-89 of the instant application, the claimed invention of the instant application would have been *prima facie* obvious over claims 1-7 of U.S. Patent No. 6,544,959 B1.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635